

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the January 1999 list were published in the Federal Register during October 1999.

Supplemental Approvals

NADA Number: 140-819

This supplemental application provides for revised feeding instructions. It also provides for the reclassification of the parasite *Triodontophorus* spp. from the large to the small strongyles in the indication section.

Trade Name: Strongid® 48
Ingredients: Pyrantel tartrate
Sponsor: Pfizer, Inc.
Approval Date: August 24, 1999
Status: Over-the-counter
Route: Oral
Species: Horses
Drug Form: Type A Medicated Article to make Type C medicated feed.
Concentration: 48 grams per pound of Type A Medicated Article
Indications: For the prevention of *Strongylus vulgaris* larval infestation in horses and for control of the following parasites.
Large strongyles (adults): *S. vulgaris*, *S. edentatus*
Small strongyles (adults and fourth-stage larvae): *Cyathostomum* spp., *Cylicocyclus* spp., *Cylicostephanus* spp., *Cylicodontophorus* spp., *Poteriostomum* spp., *Triodontophorus* spp.
Pinworms (adults and fourth-stage larvae): *Oxyuris equi*
Ascarids (adults and fourth-stage larvae): *Parascaris equorum*

21CFR 558.485

Suitability Petition Action

Number: 99P-4167/CP1
Sponsor: A & G Pharmaceuticals, Inc.
Petition: Request permission to file an ANADA for a generic new animal drug, phenylbutazone, which differs from the pioneer product, Phenylbute™, Phoenix Scientific Inc., NADA 091-818 by the following characteristic: the proposed generic product will have a dosage form as a powder as opposed to the pioneer product which is a tablet.

Action: Filed on September 20, 1999

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